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File No. 16051-10US CC/DBB/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Andrew VAILLANT et al.
Serial Number: 10/661,355
Filing Date: September 12, 2003
For: METHOD FOR IDENTIFYING ANTIVIRAL
OLIGONUCLEOTIDES
Art Unit: 1648
Examiner: HURT, Sharon L.
Agent: Saffman, Emma Direct Line: (514) 847-4337

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
U. S. A.

Sir:

Enclosed herewith is Form PTO/SB/33, i.e. a Pre-Appeal Brief Request for Review. Please consider the reasons set out below for which the review is being requested.

A Notice of Appeal is being filed concurrently.

REASONS:

The amendment filed April 24, 2006 was objected to under 35 U.S.C. 132(a) as introducing new subject matter in the disclosure. Claims 1-4, 6-7, and 10-17 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The Examiner specifically mentioned in the Official Action dated February 5, 2007, that the added material, which is not supported by the original disclosure, needs to be cancelled. More specifically, the added material is as follows: "the oligonucleotide binds to one or more viral proteins, wherein said viral protein is different from a retroviral nucleocapsid protein, meaning that the viral component is not a retroviral nucleocapsid protein". Upon cancellation of the new matter of amended claim 1, rejection of claims 1-4, 6-

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7 and 10-17 under 35 U.S.C. § 102(a & e) as being anticipated, or in the alternative, under 35 U.S.C. § 103(a) as being obvious over Rein *et al.* (US Patent No 6,316,190), will be reinstated. Following the response filed May 2, 2007, the Examiner further stated in an office communication dated June 13, 2007, that the amendment to the claims as submitted on May 2, 2007 would require an additional search in the art and re-instatement of rejections under 35 U.S.C. § 103(a). Thus, the proposed amendment was not entered.

In this regard, the Applicants wish to respectfully point out that paragraph [0068] on page 16 and claim 1 have been amended to delete the expression "is different from a retroviral nucleocapsid protein" in the last response filed May 2, 2007. Thus, the new subject matter identified by the Examiner has been deleted. In addition, claim 1 has been further amended to specify that the viral component is of a virus of the family selected from the group consisting of herpesviridae, poxviridae, hepadnaviridae, arenaviridae, bunyaviridae, coronaviridae, filoviridae, flaviridae, orthomyxoviridae, paramyxoviridae, rhabdoviridae and togaviridae. Support for this amendment can be found throughout the application and, more particularly, in paragraph [0083] and Examples 1-3 and 5-8, of the present description.

The Applicants believe that the limitation added in claim 1, more precisely defining that the viral component is of a virus of the family selected from the group consisting of herpesviridae, poxviridae, hepadnaviridae, arenaviridae, bunyaviridae, coronaviridae, filoviridae, flaviridae, orthomyxoviridae, paramyxoviridae, rhabdoviridae and togaviridae, does not represent new subject matter. As mentioned previously, support can be found in paragraph [0083] and Examples 1-3 and 5-8, of the present description.

Secondly, claim 1 was amended to include a limitation, not to broaden the scope of the claim.

Furthermore, it is believed that the Examiner initially conducted a search on subject matter directed to any oligonucleotide binding to at least one viral component of any virus. The initial search conducted by the Examiner was not restricted to specific families of viruses. Thus, the Applicants are of the opinion that by restricting the subject matter claimed in claim 1 to only encompass oligonucleotide binding to a viral component of a virus of the

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family selected from the group consisting of herpesviridae, poxviridae, hepadnaviridae, arenaviridae, bunyaviridae, coronaviridae, filoviridae, flaviridae, orthomyxoviridae, paramyxoviridae, rhabdoviridae and togaviridae, and wherein the binding of said oligonucleotide occurs principally by a sequence independent mode of action, it should not require the Examiner to conduct an additional search in the art since the subject matter claimed in amended claim 1 was already encompassed in the initial search conducted by the Examiner.

Despite the above, the Applicants wish to also submit that contrary to the teaching found in the present application and as already acknowledged by the Examiner, Rein *et al.* only teaches assays where target molecules are assessed for their ability to inhibit binding of retroviral nucleocapsid proteins to selected nucleic acids (oligonucleotides). A person skilled in the art would acknowledge that retroviral nucleocapsid proteins are only found in retroviruses. Retroviruses are enveloped viruses possessing an RNA genome. Thus, a person skilled in the art would also acknowledge that results demonstrating the efficacy of a molecule to inhibit the binding of the retroviral nucleocapsid can only be used to predict the ability of the molecule to inhibit infection of retroviruses and not of other viruses. For example, contrary to DNA viruses, retroviruses replicate using a reverse transcription. Accordingly, results demonstrating the efficacy of a molecule to inhibit the binding of the retroviral nucleocapsid can only be used to predict the ability of the molecule to inhibit infection of retroviruses and not of other viruses like DNA viruses. In the assays disclosed in Rein *et al.*, retroviral nucleocapsid proteins, oligonucleotides comprising a substance which binds to a retroviral nucleocapsid protein with high affinity, and a target molecule are mixed, and the inhibitory effect on nucleocapsid-oligonucleotide binding is measured. Nowhere is it taught or even suggested in Rein *et al.* that oligonucleotides have an antiviral activity against other viruses, such as viruses of the families now claimed in amended claim 1. Thus, since Rein *et al.* only discloses oligonucleotides which bind to retroviral nucleocapsid proteins, it is believed that the present application is new and inventive in view of the teaching of Rein *et al.*

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In view of the arguments and amendments submitted hereinabove, the Applicants respectfully submit that the 35 U.S.C. 112, first paragraph, rejection or 35 U.S.C. §103(a) rejection, is improper, and request that it be withdrawn. Furthermore, the Applicant request that the amendment filed May 2, 2007 be entered.

It is submitted, therefore, that the claims are in condition for allowance, and prompt and favorable action in the form of a Notice of Allowance is earnestly solicited.

Respectfully submitted,

Date: August 3, 2007By: 

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CERTIFICATE OF FACSIMILE TRANSMISSION

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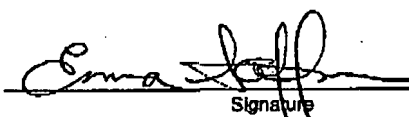
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PTO/SB/33 (07-05)

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		First Named Inventor Andrew VAILLANT	
		Art Unit 1648	Examiner HURT, Sharon, L.
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.			
I am the <input type="checkbox"/> applicant/inventor. <input type="checkbox"/> assignee of record of the entire interest. Sec 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/98) <input checked="" type="checkbox"/> attorney or agent of record. 56,699 Registration number _____ <input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____		 Signature Emma Saffman Typed or printed name (514) 847-4337 Telephone number _____ Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			
<input checked="" type="checkbox"/> *Total of 3 forms are submitted.			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.8. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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